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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,604	04/08/2004	Michel Gilbert	019633-000129US	1518

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,604	GILBERT ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-51* is/are pending in the application.

4a) Of the above claim(s) *44-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43 and 49-51* is/are rejected.

7)☐ Claim(s) *51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0404;1204*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

Applicant's election, without traverse, of Invention I, Claims 43 and 51, in part, and Claims 49 and 50, in their response of September 18, 2006 is acknowledged. It is noted that Claim 51, reciting a polynucleotide, was inappropriately grouped with the elected invention, directed to a protein encoding a β1,4-N-acetylglucosaminyl transferase. Nonetheless, in the interest of public service and compact prosecution, Claim 51, as encoding the elected protein, will be herein examined. Claims 43-51 are pending. Claims 44-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claims 43 and 40-51 are hereby examined.

Priority

The priority date of the instant invention is taken to be April 8, 2004, the filing date of the instant application. US Application 10/303,128 does not disclosed a β1,4-N-acetylglucosaminyl transferase encoded by a polynucleotide that can be generated from a Campylobacter sp. using the primers set forth by SEQ ID NO: 40 and 41.

Title

The title is objected to because it is not descriptive of the elected invention.

Abstract

The Abstract is objected to because it is not descriptive of the elected invention.

Information Disclosure Statement

Parts of the Information Disclosure Statement filed April 7, 2004 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. Copies of initialed Information Disclosure Statements and Examiner provided 892 forms from other applications do not comply with 37CFR 1.98(a)1 (see MPEP 609.05(a)(b)). The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. If Applicants wish for the references therein to be considered, a supplemental Information Disclosure Statement should be submitted. Any subsequent rejection, based on consideration of the supplemental Information Disclosure Statement, will not be considered a new grounds for rejection.

Specification-Objections

The first paragraph of the specification should be updated to reflect the current status of all priority documents stated therein.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e, via an issued patent, to link to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs,

are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

Claims-Objections

Claim 51 is objected to for reciting non-elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Claims 49-51 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Applicants have asserted, in said claims, that the elected polypeptide, having β1,4-N-acetylglucosaminyl transferase activity, is encoded a Campylobacter nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41. The claims, specification, and the prior art fail to provide any evidence that supports said assertion. The instant disclosure does not teach a polypeptide having β1,4-N-acetylglucosaminyl transferase activity or any polynucleotide that encodes such a polypeptide. Moreover, the Office failed to find evidence in the art that any Campylobacter cell expresses β1,4-N-acetylglucosaminyl transferase activity. Therefore, the elected invention does not have a specific and substantial patentable utility.

Claims 49-51 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 43 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3 of US Patent 6,210,933, Claims 1-7 of US Patent 6,825,019, and Claims 1 and 3-5 of US Patent 7,078,207. In each case, although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 43 herein and Claims 1-3 of 6,210,933, Claims 1-7 of 6,825,019, and Claims 1 and 3-5 of 7,078,207 are each directed to proteins having glycosyltransferase activity, wherein the protein is encoded a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from a Campylobacter cell. The claims differ in that Claims 1-3 of 6,210,933 specifically recite α2,3-sialyltransferase activity, Claims 1-7 of 6,825,019 specifically recite β1,3-galactosyltransferase activity, and Claims 1 and 3-5 of 7,078,207 specifically recite β1,4-acetylgalactosaminyltransferase activity, while Claim 43 herein recites any glycosyltransferase

activity. The portion of the specifications in 6,210,933, 6,825,019, and 7,078,207 that supports the recited proteins includes embodiments that would anticipate Claim 43 herein, e.g., proteins having any glycosyltransferase activity, which are also the proteins specifically recited in the claims of the issued patents. Claim 43 herein cannot be considered patentably distinct over the claims of the issued patents when there are specifically recited embodiments (proteins having any glycosyltransferase activity) that would anticipate Claim 43 herein. Alternatively, Claim 43 herein cannot be considered patentably distinct over the claims of the issued patents when there are specifically disclosed embodiments in 6,210,933, 6,825,019, and 7,078,207 that supports the claims of those issued patents and falls within the scope of Claim 43 herein, because it would have been obvious to a skilled artisan that the specific proteins recited therein are encompassed by the invention elected herein.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 49-51 are rendered indefinite by the abbreviation "GalNAc", which is the abbreviation for β1,4-N-acetylglucosaminyl transferase, not β1,4-N-acetylglucosaminyl transferase. It is unclear whether a protein having β1,4-N-acetylglucosaminyl transferase activity or β1,4-N-acetylglucosaminyl transferase activity is being recited. For purposes of examination, it is assumed that β1,4-N-acetylglucosaminyl transferase activity is being recited.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Even if Claims 49-51 were not rejected under 35 U.S.C. 101/112, for the reasons described above, the following rejection would be made.

Claims 43 and 49-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while be enabling for the proteins of ORFs 5a, 6a, and 7a (Table 3), does not reasonably provide enablement for any protein having any glycosyltransferase activity, or specifically β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill

of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claim 43 is so broad as to encompass any protein having any glycosyltransferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. Claims 49 and 50 are so broad as to encompass any protein having any β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. Claim 51 is so broad as to encompass any polynucleotide encoding the protein of Claim 49. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins and polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the specification discloses only three proteins from one strain of Camplobacter that have glycosyltransferase activity and fails to disclose any protein having β1,4-N-acetylglucosaminyl transferase activity or any polynucleotide encoding any protein having β1,4-N-acetylglucosaminyl transferase activity.

While PCR techniques and assays for measuring glycosyltransferase activity are known, it is not routine in the art to generate an essentially unlimited number of nucleic acid molecules from an essentially unlimited number of Campylobacter cells and test whether said nucleic acid

molecules encode any protein having any type of glycosyltransferase activity or β1,4-N-acetylglucosaminyl transferase activity. Moreover, the specification teaches the unpredictability of isolating the desired proteins and that the expectation of success is low. For example, the specification clearly states that the size of the LOS locus is different for between two types of Campylobacter cells (pg 53, parg 4) indicating that there is little expectation of success in generating the desired nucleic acid molecules using the recited primers. Furthermore, the specification states that the function for any putative glycosyltransferase genes in the LOS of Campylobacter jejuni NCTC 11163 strain is impossible to predict (pg 53, parg 3). Therefore, a high level of guidance is required for the skilled artisan to make and used the recited invention. Such guidance is not provided.

The specification does not support the broad scope of Claim 43, which encompasses all proteins having any glycosyltransferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. The specification also does not support the broad scope of Claims 49-51, which encompasses all proteins having β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell, or the encoding polynucleotide. The specification does not support the broad scope of Claims 43 and 49-51 because the specification does not establish: (A) the structure of any protein having any β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from and Campylobacter cell; (B) the structure of any polynucleotide that encodes a protein having or β1,4-N-acetylglucosaminyl transferase activity, wherein the polynucleotide can be

generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from and Campylobacter cell; (C) the specific type of glycosyltransferase activity of all proteins that are encoded by any polynucleotide that can be generated from any Campylobacter cells using the recited primers; (D) which Campylobacter cells can be used with the recited primers to generate nucleic acid molecules encoding proteins with the desired activity; (E) a rational and predictable scheme for isolating proteins with the desired activity; and (F) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any protein having any glycosyltransferase activity, or specifically β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded by a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the

claimed invention. These claims are directed to a genus of proteins having any type of glycosyltransferase activity and any structure, wherein the protein can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. The specification does not contain any disclosure of the structure or function of all said proteins. The genus of polypeptides that comprise these above proteins is a large variable genus with the potentiality of having many different structures and types of glycosyltransferase activities. Therefore, many structurally and functionally unrelated proteins are encompassed within the scope of these claims. The specification discloses the structure and function of only three species of the claimed genus (Table 3), which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 49 and 50 are directed to a genus of proteins having β1,4-N-acetylglucosaminyl transferase activity, wherein the protein is encoded a nucleic acid molecule that can be generated by PCR using the primers of SEQ ID NO: 40 and 41 and DNA from any Campylobacter cell. Claim 51 is directed to a genus of nucleic acid molecules encoding said proteins. The specification teaches the structure of only a single representative species of such

proteins or nucleic acid molecules. Moreover, the specification fails to describe any species by any identifying characteristics or properties other than the functionality of the protein having β1,4-N-acetylglucosaminyl transferase activity and the nucleic acid molecule encoding said protein. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER